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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/237,605 01/25/99 LAZZARA

R IMPI.035-1

EXAMINER

QM12/1220

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PRELIMINARY	
ART UNIT	PAPER NUMBER

3738

DATE MAILED:

12/20/00

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/237,605

Applicant(s)
Lazzara et al

Examiner
Paul Prebilic

Group Art Unit
3738



☒ Responsive to communication(s) filed on Nov 30, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 11-50 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 11-50 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Continued Prosecution Application

The request filed on November 30, 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/237,605 is acceptable and a CPA has been established. An action on the CPA follows.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It was not executed in accordance with either 37 CFR 1.66 or 1.68. Specifically, the declaration filed October 13, 2000 does not provide the date which Keith D. Beaty signed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession

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of the claimed invention. The terminology “substantially” to described the degree to which the native oxide layer is removed or the uniformity of the roughness lacks original support and/or there is no guidance as to its affect on the metes and bounds of the claim language. Since there is not guidance in the original specification, it appears that even a bulk etched metal implant surface would be substantially uniform in roughness and substantially free of the native oxide layer. Moreover, “substantially” is a broad term. *In re Nehrenberg*, 126 USPQ 383 (CCPA 1960) and see MPEP 2173.05(b) which is incorporated herein by reference. The specification fails to provide some standard for measuring that degree. Therefore, one of ordinary skill would not know what degree of roughness or native oxide layer would fall within the claim scope and what would not. The controlling case law appears to be that of *In re Mattison*, 184 USPQ 383 (CCPA 1960). It states:

We are not persuaded by the board's reasoning that one skilled in the art would not be able to determine the scope of the claimed invention in terms of a specified percentage value. General guidelines are disclosed for a proper choice of the substituent Ep together with a representative number of examples. (emphasis added here)

The Board of Appeals was reversed because there were general guidelines as to what constituted a substantial increase. This is not the situation here where there are no guidelines in the specification, and the prior art does not give one a clear picture as to what constitutes a substantially uniform roughness or a surface substantially free of native oxide and what does not. This is a critical and defining limitation of the claim and it must be clear as to what falls within its scope.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The scope of the claims are indefinite because of the ambiguity presented by the "substantially" terminology discussed in the 35 USC 112, first paragraph rejection.

The information disclosure statement was more completely considered in response to Applicants' providing a copy of most of the missing references. However, the Examiner still could not consider the Swiss patent because no copy was provided in the most recent set. The Branemark article could not be considered because only the cover pages of the article were provided and not the article itself.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-16, 22-25, and 27-49 are rejected under 35 U.S.C. 102(b) as anticipated by Krueger (US 4,826,434) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Krueger (US 4,826,434) alone. Krueger anticipates the claim language wherein Krueger teaches a threaded surface intermediate product which has been etched to remove impurities; see the whole document, especially Figure 3 and Col. 3, line 38 to Col. 4, line 7. The Examiner asserts that at least one of the intermediate product (Col. 3, lines 50-56) and the final etched product would have their native oxide layers removed and would have irregularities of less than 10 microns approaching 0 microns.

Alternatively, it is not clear that the intermediate product surface has a native oxide layer removed, but the Examiner posits that the etching process to increase the surface area by two would obviously remove the native oxide layer to the extent claimed and the Examiner hereby burdens Applicant to show that the product disclosed by Krueger does not meet or obviate the claimed invention. Since the Office does not have facilities to test the prior art against the Applicant's invention, it is the Examiner prerogative to burden the Applicant to do the same when certain physical properties appear to be present in the prior art even though not explicitly taught thereby.

With regard to claims 12, 25, 28, 38, 46, and 47, the Examiner posits that since the same etching process is used to form irregularities on the surface of the same material as claimed that

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the surface irregularities of Krueger would inherently be the same as those set forth in the claims; i.e. cone shaped.

With regard to claims 13 and 36, the Examiner posits that the claimed process steps result in the same invention such that the claimed invention is at least clearly obvious in view thereof. The Examiner is also under a lesser burden to show that process limitations in product claims are met; see MPEP 2113 which is incorporated into this Office action by reference thereto.

With regard to claim 34, the Examiner takes the position that smooth is a term of relative degree such that even the etched surfaces of Krueger are smooth to the extent required by the claims. The Examiner notes that there is no comparison of the smooth surface recited in this claim to other surfaces of the same implant.

Claims 26 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krueger as applied to claims 11-16, 22-25, and 27-49 above, and further in view of Wagner et al (US 5,989,027). Krueger at least obviates the claim language as set forth in the above rejection but fails to teach both a roughened region and an unroughened or other region as required by the claims. Wagner et al teaches that it was known in the art to have different regions of roughness; see the entire document. Hence, it is the Examiner's position that it would have been obvious to have a smoother head portion in the Krueger invention for the same reasons that Wagner et al has the same.

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Response to Arguments

Applicant's arguments filed October 13, 2000 have been fully considered but they are not persuasive.

In response to the Applicant's traversal of Krueger that Krueger did not remove the native oxide layer, the Examiner posits that mere treatment of the titanium surface renders the surface layer, including any oxide layer thereon, non-native. Furthermore, the claims allow for a broad interpretation of the native oxide layer remaining and the roughness uniformity because of the use of "substantially" in association with these limitations. That is, even if an oxide layer still exists on Krueger after oxide treatment, than it could no longer be considered native because it has been treated with mineral acid to the extent that the surface area has been doubled. Such an extensive etching would inherently alter or remove most if not all the native oxide layer such that a substantial native oxide layer would no longer exist on the surface.

Furthermore, the Examiner posits that the Applicant is merely claiming a newly discovered feature of an old article. However, something old does not become patentable because a new property of feature is discovered thereon; see MPEP 2112 which is incorporated herein by reference thereto.

In response to the traversal that the smooth surface should be understood as relative to another portion of the device, the Examiner respectfully disagrees and takes the position that the claim does not make a comparison the smoothness with respect to another portion. For this reason, the argument is not commensurate with the scope of the claim language.

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In response to the traversal of the rejection utilizing Wagner et al, the Examiner posits that Wagner et al is not contradictory to Krueger and that Wagner et al properly teaches Krueger that relatively smooth and rough portions would have been obvious to an ordinary artisan.

Applicants argue that he cannot make a comparison of the present invention with Krueger because of the lack of detail therein. Applicant further states that a search of the patent literature was made and it did not locate any information pertaining to electrolytic capacitors. The Examiner is surprised that Applicant could find no such information. The Examiner performed an electronic database search of "etch or etching or etched" in the same paragraph as "capacitor or electrode" and got 53,638 hits; see the attached copy of the database search. An additional search was performed requiring that the etch variants and "capacitor or electrode" be in the same sentence along with "mineral acid" in the same paragraph and the Examiner got 9 hits. At least 4 of these hits were quite relevant and three have been attached to the attached database search. Possibly, Applicants could use this information as a basis for doing a comparative test.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vincent Millin, can be reached on (703) 308-1065. The fax phone number for this Technology Center is (703) 305-3580.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read "Paul Prebilic", with a stylized flourish at the end.

Paul Prebilic
Primary Examiner
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